OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

<table>
<tr><td colspan="4">Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.</td></tr>
<tr><td>RFP Number:

NIH-NIAID-DAIT-02-04</td><td>Just In Time:

[ ] Yes
[X] No</td><td>Small Bus. Set-Aside [ ]Yes [X]No
8(a) Set-Aside [ ]Yes [X]No
NAICS Code: 54171
Size Standard: 500 employees</td><td>Level of Effort:
[ ] Yes [X] No
Total Effort:
[N/A]</td></tr>
<tr><td colspan="4">TITLE: NIAID Tetramer Facility</td></tr>
<tr><td colspan="2">Issue Date: March 9, 2001</td><td>Due Date: July 9, 2001
Time: 2:00 PM, EST</td><td>Technical Proposal Page Limits:
[X] No
(see “How to Prepare and Submit Electronic Proposals”)</td></tr>
<tr><td rowspan="2">ISSUED BY:
Barbara A. Shadrick
Contracting Officer
Contract Management Branch, DEA, NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612</td><td colspan="3">[X] We reserve the right to make awards without discussion.</td></tr>
<tr><td>NO. OF AWARDS:

[X] Only 1 Award
[ ] Multiple Awards</td><td colspan="2">PERIOD OF PERFORMANCE:

5 years beginning on or about 11/30/2001</td></tr>
<tr><td colspan="4">Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled “Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)</td></tr>
<tr><td colspan="4">The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. If your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR Clause 352.215-70 entitled “Late Proposals and Revisions” located in this Solicitation.</td></tr>
<tr><td colspan="4">POINT OF CONTACT -- Lois Eaton --COLLECT CALLS WILL NOT BE ACCEPTED--</td></tr>
<tr><td colspan="2">Telephone: Direct 301-496-0611
Main 301-496-0612</td><td>Fax 301-402-0972</td><td>E-Mail le52u@niaid.nih.gov</td></tr>
</table>

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BACKGROUND

Introduction

The National Institute of Allergy and Infectious Diseases (NIAID) supports reagent programs and repositories that provide centralized resources for the research community. These facilities support research by providing reliable sources of quality-assured materials, specimens, or experimental animals at reasonable cost to qualified investigators. The NIAID posts information on reagent programs at **http://www.niaid.nih.gov/reposit/default.htm**.

The NIAID Tetramer Facility, established at Emory University in 1998 under the direction of John Altman, Ph.D., serves the scientific community as a centralized source of quality-controlled tetramer reagents for basic, preclinical, and clinical research. The NIAID Division of AIDS oversees the Facility, which is a subcontract to the AIDS Research and Reference Reagent Program contract N01 AI 85332, with McKesson BioServices. McKesson BioServices included the NIAID Tetramer Facility as a subcontract following a sole source solicitation based upon the unique capabilities of Dr. Altman's group at Emory University. The NIAID Division of AIDS, the Division of Microbiology and Infectious Diseases, the Division of Intramural Research, the Division of Allergy, Immunology and Transplantation, as well as the National Cancer Institute provided funding for the Facility for the period FY 1999-FY 2001.

Twice monthly, the NIAID Tetramer Resource Committee, comprised of NIAID scientific Staff, reviews requests submitted at the Facility website **http://www.niaid.nih.gov/reposit/tetramer/index.html**. The website also details the scientific evaluation criteria used in the review of tetramer reagent requests under the heading "Request Prioritization." Upon approval of requests by the NIAID Tetramer Resource Committee, the Project Officer instructs the Contractor to notify approved requestors to send the required peptides to the Facility, which requestors must supply for custom syntheses, and to pre-pay the shipment of the reagents. The cost of the peptides and shipping are the only expenses borne by the requestors. The Facility supplies tetramer reagents that contain user-specified fluorescent labels and are ready to use. The Facility website lists the specifications and guidelines for use of tetramer reagents provided by the Facility under "General Guidelines." To date, the Facility has:

(1) provided over 560 tetramer reagents, comprising human, murine, and non-human primate MHC alleles;
(2) supplied tetramer reagents to researchers at non-profit organizations both in the U.S. and abroad, including investigators supported by ten NIH Institutes, the Food and Drug Administration, the Department of Defense, the Centers for Disease Control and Prevention, and private non-profit U.S. foundations, as well as to researchers in Europe, Australia, Israel, and Canada;
(3) produced tetramers applicable to a wide range of T cell studies, including research on AIDS and other infectious diseases, cancer, organ transplantation, autoimmunity, clinical vaccine evaluation, and basic studies on T cells and immune responses; and
(4) developed standardized methodology for tetramer usage and evaluated new advances in tetramer design and production to assure that the Facility's reagents reflect state-of-the-art capabilities.

Background

The ability to detect, measure, and isolate T cells that respond to specific antigens is central to understanding and controlling immune responses. Until recently, however, cumbersome functional assays requiring many days of cell culturing were the only techniques available to estimate the magnitude and specificity of T cell responses. Dr. Mark Davis and collaborators [Altman et al., Science 274: 94-96 (1996)] established a technique that enables the rapid identification of T cells in peripheral blood or other tissues. They showed that multimeric, especially tetrameric, peptide-MHC complexes bind to T cell antigen receptors, permitting detection and enumeration of antigen-specific T cells by flow cytometry. An increasing number of important publications indicate that this technique is very robust and precise; data obtained by this method are revolutionizing the understanding of T cell responses. For example, detection with tetrameric peptide-MHC complexes revealed that cytotoxic T cell responses to viral infection are many times higher than previously believed, with cells recognizing immunodominant epitopes constituting, in some cases, 50% or more of the total CD8+ T cells in lymphoid organs. This methodology lends itself to many types of basic and clinical studies of T cells, permitting accurate measurements of the kinetics, distribution, and phenotypic composition of antigen-specific T cell responses. Because T cells are central to virtually all immune responses, this technology is applicable to studies in many areas, including infectious diseases, vaccination, autoimmunity, transplant rejection, and tumor therapy. In addition to T cell detection, other proposed novel applications of tetramer technology include targeting therapeutic compounds to enrich or remove antigen-specific T cells *in vivo*, and visualization of antigen-specific T cells in tissue sections.

Tetramer reagent production requires both molecular biology and protein biochemistry techniques. Typically, reagent synthesis begins with the expression of MHC class I molecules in bacteria using a recombinant plasmid that encodes an additional sequence that is the target of the biotinylating enzyme Bir-A. Bir-A adds a single biotin molecule at a specified amino acid location to monomeric peptide-MHC complexes, which form by refolding purified MHC heavy chain protein and the beta-2 microglobulin light chain in the presence of the desired peptide. The biotinylated monomers become oligomerized into tetramers by reaction with avidin, a tetravalent molecule. The avidin generally contains a fluorescent label for detection in automated cytometry devices or by microscopy. Quality control procedures to ensure that the reagent will function in cellular assays include analyses by high-performance liquid chromatography and immunological testing.

The demand for these multimeric peptide-MHC reagents will increase as a result of widespread acceptance of the technology as a standard assay for T cells. Production of MHC class II tetramers on a routine basis will further enlarge the application of the methodology by enabling the accurate measurement of helper T cells in addition to the cytotoxic T cells detectable by the current class I MHC tetramer reagents. Beckman-Coulter, Inc., has licensed the patented tetramer reagent technology. However, in the near future, commercial production will not provide the wide range of tetramers required for research studies in many diverse areas. Currently, Emory University is the only laboratory that has the depth of experience and willingness to efficiently produce these reagents, which requires, in particular, strong expertise in protein refolding and in quality control.

STATEMENT OF WORK
RFP NIH-NIAID-DAIT-02-04
"NIAID Tetramer Facility"

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below.

Specifically, the Contractor shall:

A. **Operate and maintain a centralized tetramer reagent facility** to produce and ship quality controlled, custom synthesized tetrameric antigen/major histocompatibility complex (MHC) molecules for use by qualified investigators to detect, enumerate and isolate antigen-specific T cells. MHC molecules may include any of the alleles of mammalian class I, class II, and non-classical MHC molecules. The Contractor shall establish production capacity for approximately 15-20 tetramer reagents per week. The Contractor shall also develop a plan to increase production capacity up to 30 tetramer reagents per week to accommodate potential increases in requests. The Contractor shall provide each requestor with approximately 0.2 milligrams of the final tetramer reagent product.

The Contractor shall:

1) Produce recombinant MHC proteins in vitro: The Contractor shall clone and express genes for human, rodent, non-human primate or other mammalian species' class I, class II, and non-classical MHC molecules, as well as human, rodent, non-human primate or other mammalian species' beta-2 microglobulin. Genetic cloning procedures shall include the introduction of structural modifications to the genes encoding the MHC molecules to enable labeling by the Bir-A enzyme, and, where required, to enhance the stability of the molecules, such as by incorporation of leucine zipper sequences. The Contractor shall express the proteins in appropriate microbial, insect, or mammalian cell lines as needed according to the specific vectors employed and the desired form of the MHC molecules.

2) Purify recombinant MHC proteins: The Contractor shall isolate the expressed proteins from bacterial inclusion bodies, cell lysates, cell supernatants, or other fractions. The Contractor shall optimize chromatography and other purification methods for efficient extraction, purification, and concentration of the isolated product for high yield renaturation.

3) Fold peptides into MHC proteins: The Contractor shall renature (fold) the MHC-peptide complexes to yield the most efficient incorporation of peptides or other ligands into the antigen-binding groove of the purified MHC proteins, forming fully refolded and stable complexes of ligand, MHC heavy chain, and beta-2 microglobulin. Using analytical procedures, the Contractor shall monitor the folding reaction and quantitate the yield of correctly folded products.

4) Biotinylate MHC/peptide complexes: The Contractor shall quantitatively incorporate biotin at MHC molecule amino acid side chain residues that are non-critical for peptide, T cell receptor, or CD8/CD4 receptor interaction, using Bir-A enzyme or other methodology.

5) Complex biotinylated MHC/peptide to specified fluorochromes to produce tetrameric staining reagents: The Contractor shall react renatured, biotinylated MHC-peptide monomers with appropriate fluorochrome-avidin conjugates required for the requestor's use as specified in the approved request. The Contractor shall test commercial lots of avidin-fluorochromes such as avidin-phycoerythrin, avidin-allophycocyanin, and other fluorescent conjugates in common use for their ability to produce labeled tetramers that shall have a high degree of oligomerization and high fluorescence specific activity.

6) Establish quality control standards and implement quality control procedures for all reagents produced to ensure purity and product functionality and the provision of reliable, reproducible reagents to requesting investigators. The Contractor shall analyze each product batch using appropriate tests, including, but not limited to enzyme-linked immunosorbent assays with antibodies to beta-2 microglobulin to verify proper complex formation, and fast protein liquid chromatography to characterize the product's molecular size as an indicator of its proper folding and complex formation. The Contractor shall release only batches that pass these tests.

7) Participate in discussions with representatives of the NIH and Beckman-Coulter, Inc., as instructed by the Project Officer, to determine whether the Contractor will supply specific tetramer reagents or whether Beckman-Coulter will make them available commercially.

B. Operate a distribution, tracking, and reporting system for all reagents requested.

The Contractor shall:

1) Receive approved requests for tetramer reagents from the Project Officer, including specifications for frequently requested tetramers to be synthesized and used to fill orders from stock. The Contractor shall establish a standard operating procedure (SOP) for the administrative and manufacturing activities associated with each approved request. This SOP must include a checklist for the managerial and technical actions needed to initiate and complete each order. Action on each approved request shall begin not later than 7 calendar days after receipt of the request order by the Contractor.

2) Obtain approvals, assurances, and materials necessary to distribute reagents. The Contractor shall send to and verify receipt from requestors of a signed official registration form certifying requestor compliance with safety standards, animal and human subjects protection regulations, pre-payment of shipping costs, use in non-profit research by the requestor only, acknowledgement of the Facility in publications, reporting requirements, and other information as specified by the Project Officer. The Contractor shall request and receive 10 milligrams of HPLC-purified peptides from requestors as needed to produce custom tetramer reagents.

3) Contact approved requestors regarding fulfillment of orders. This includes specifying the peptides that the requestor will supply, identifying genetic plasmids that the requestor must provide, and the availability of specific fluorochromes. The Contractor shall also respond within 7 days to requestor queries regarding the status of orders.

4) Distribute reagents to approved investigators according to NIH operational procedures specified above within one week of completion of quality control testing. Requesting investigators will pre-pay for express parcel delivery costs. The Contractor shall provide shipping containers and wet ice packs or dry ice as appropriate, and ship the product by express parcel delivery to the appropriate address. The shipping procedure shall include providing the appropriate package handling and customs documentation for domestic and foreign destinations. A package insert describing the results of quality control testing of the specific reagent and a description of the product, including identification of the MHC molecule and peptide, fluorescent label, protein concentration, buffer, and suggested use protocol shall accompany each product. In certain cases where tetramers may be unstable during prolonged transit times on wet ice, for example shipments to foreign locations, the Contractor shall ship monomeric biotinylated MHC-peptide complexes on dry ice for the user to constitute to tetramers with avidin.

5) Maintain a computerized database to track all tetramer reagent requests received, pending, and filled, and to manage an inventory of reagents and materials. The database shall use commercially available personal computer software.

6) Maintain an updated website of public information on reagent availability, technical specifications, the request, review, and order fulfillment process, and use protocols. The website shall include a list of available pre-made tetramer reagents and available fluorescent conjugates. Website contents shall require the approval of the NIAID Office of Communications and the Project Officer.

7) Provide a status report to the NIAID Tetramer Resource Committee on a monthly basis.

C. Identify, develop, and incorporate new processes, approaches, and technologies to ensure a state-of-the art tetramer reagent production facility.

The Contractor shall:

1) Optimize current manufacturing methods to improve the production, quality control and reliability of tetramer reagents. The Contractor shall analyze data from quality control testing, batch production efficiency, feedback from investigators who use tetramer reagents supplied by the Facility, and other relevant information, such as published data, to identify problems occurring in tetramer reagent design, production, and usage, and their likely causes. The Contractor shall identify problems, propose solutions, and implement modifications to ensure efficiency and quality with respect to the production, testing, and handling routines.

2) Evaluate new methodologies to improve upon or replace tetramers as T cell reagents. The Contractor shall obtain or synthesize reagents that may have improved properties over the current tetramer reagent technology, and evaluate these directly in comparison with the current reagents.

3) Sponsor annual workshops to develop new reagents, improve and standardize use protocols, and promote technology transfer. In consultation with the Project Officer, the Contractor shall annually identify key contributors to the tetramer technology field and invite them to participate in a workshop. The costs for invited participants and costs associated with holding the workshop shall be reimbursed under the contract. The Contractor shall post an executive summary of the workshop on the NIAID Tetramer Facility website within 8 weeks of the completion of the workshop.

[END OF STATEMENT OF WORK]

NOTES TO OFFERORS

NOTE 1

Subcontracting agreements are acceptable and encouraged to accomplish the work outlined in this solicitation. The proposal must describe in detail a management plan detailing how the Contractor will coordinate the work of the Subcontractor(s). The proposal must also include the Subcontractor's contribution to the overall proposal, and the complete description of all Subcontractor's facilities, professional background of personnel, and cost.

NOTE 2

Disclosures of any and all patents or patent applications of materials, reagents, animal models, or procedures filed in or outside the US by the offerors and/or listed personnel or collaborators must be made at the time of proposal submission.

NOTE 3

The following assumptions are provided for technical proposal preparation purposes:

1. To estimate time and costs of tetramer production, the offeror may justify an average refolding efficiency for MHC molecules. The offeror should include in their proposal approaches to troubleshoot production procedures and processes to achieve production goals.

2. The offeror should include a plan in the proposal to increase tetramer reagent production capacity to 30 tetramer reagents per week. The plan should identify associated costs, but these costs should not be included in the proposed budget.

3. For the Statement of Work Paragraph B.1, the offeror should include a sample SOP in the technical proposal. The offeror should propose a system whereby applications for the same MHC alleles will be processed simultaneously to allow for more efficient batch synthesis of alleles.

4. For the Statement of Work paragraph C., the offeror should propose a set of specific aims that identify major gaps in knowledge and high priority research and development goals for maintaining a state-of-the-art tetramer reagent production facility. The offeror should indicate how the research and development activities would integrate with the reagent manufacturing activities.

NOTE 4

For budget estimating purposes, assume the following:

1. The annual workshop cost estimates should include travel costs (transportation, meals, hotel, etc.) for 20 invited participants, as well as costs associated with holding the workshop. Assume the workshop will be held in Bethesda, MD, for 1.5 days.

2. The offeror should budget travel for key personnel to attend two scientific meetings per year.

3. The offeror should indicate costs of peptides used to synthesize frequently requested tetramers. Currently, five premade tetramer reagents are available, and they comprise approximately 40% of the approved requests. Requestors will supply peptides for custom syntheses.

4. Equipment costs: assume the purchase in Year 1 of an Amersham FPLC system plus chromatography columns and fittings and small pieces of equipment, such as multichannel pipetors to be dedicated to class II MHC tetramer production.

NOTE 5

NIAID Tetramer Facility Website: http://www.niaid.nih.gov/reposit/tetramer/index.html

REPORTING REQUIREMENTS

As part of the work to be performed under this contract, the Contractor shall prepare and deliver the following reports. The exact submission schedule will be negotiated and established in the contract document.

1. Monthly Status Reports

   The Contractor shall provide within 5 working days of the end of each month one copy of a monthly status report to the NIAID Tetramer Resource Committee that summarizes the processing and fulfillment of requests.

2. Quarterly Progress Reports

   The Contractor shall submit 2 copies the 15th of the month following the end of each quarterly performance period. The original shall be submitted to the Contracting Officer, with a copy to the Project Officer. Each quarterly report shall include the following:

   (A) Face page to include contract number, contract title, performance period covered, Contractor's name and address, telephone, telefax and E-mail numbers and submission date.

   (B) An executive summary, to include:

      1) An overview of the status of the NIAID Tetramer Facility, including personnel, tetramer requests processed, research and development activity;
      2) A brief overview of the work that was completed for the reporting period and/or justification for failure to complete intended work or performance of unintended work;
      3) A brief overview of the activities that occurred during the current reporting period and any problems (technical or financial) that occurred during the current reporting period; and
      4) The fulfillment of production goals and of the specific aims set forth in the proposal.

   (C) A full description of:

      1) The work performed during the reporting period;
      2) The relation between the accomplishments and the goals and objectives of the contract; and
      3) A full discussion of the results and their relevance; explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented.

   (D) Copies of manuscripts (published or unpublished) derived from research performed under the contract and copies of all abstracts, manuscripts, preprints and publications that resulted from work conducted or any protocol or method developed specifically under this contract during the performance period.

   (E) A full disclosure of intent to file patent applications within or outside of the US on materials, reagents, animals models or procedures derived or established by the work supported under this contract; full disclosure of patent applications filed, as well as copies of patent applications.

   Quarterly Progress Reports are not required for periods in which an Annual or Final Report is due.

3. Annual Progress Reports

   The Contractor shall submit two (2) copies (as specified above) of Annual Progress Reports that document and summarize the results of the entire contract work for the period covered. This report shall be due the 30th of the month following each anniversary date of the contract. An Annual Report shall not be due when the Final Report is submitted. The report shall conform to the following format:

   (A) Face page to include contract number, title, period of performance being reported, Contractor's name and address, date of submission.

   (B) An executive summary, to include the fulfillment of production goals and of the specific aims set forth in the proposal;

(C) A detailed description of the work performed, the results obtained, and a discussion of the relevance of the results and their relation to work being conducted in the area by other groups.

4. Final Report

The Contractor shall submit two (2) copies (as specified above) of the Final Report that document and summarize the results of the entire contract period of performance. This report shall be submitted on/before the completion date of the contract. The report shall conform to the following format:

(A) Face page to include contract number, title, period of performance being reported, Contractor's name and address, date of submission.

(B) Summary of salient results. The Contractor shall submit a summary, not to exceed 200 words, of salient results achieved during the performance of the contract;

(C) An executive summary, to include the fulfillment of production goals and of the specific aims set forth in the proposal;

(D) A detailed description of the work performed, the results obtained, and a discussion of the relevance of the results and their relation to work being conducted in the area by other groups.

5. Other Deliverables

Deliverables required on or before the contract completion date: The Contractor shall return to NIH or deliver to a successor Contractor equipment supplied or procured under this contract, the complete database of tetramer requests, and all genetic, biochemical, and biological materials acquired or developed during the contract period. This includes plasmids, stocks of peptides, tetramer reagents, cell lines, and stored specimens.

6. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. In addition, for Phase III clinical trials, Section III.B of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Updated August 2, 2000, at the following website, applies:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html

A complete copy of the updated Guidelines is available at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm

A description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups shall be included in the clinical trial protocol and the results of the subset analyses must be reported in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. Inclusion of the results of subset analysis is strongly encouraged in all publication submissions.

7. Reports submitted to the Government shall not include any identifier of subjects. i.e., volunteers, patients, involved in these studies.

8. If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reason therefor.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000), Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
52.216-7	Mar 2000	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 1.2" and to add the words "Subpart 31.3")
52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)

52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General, Alternate IV (Jun 1987)
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)

52.249-5	Sep 1996	Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - Rev. 2/2001].

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: May 21, 2001 (Attached to this listing)

[NOTE: Your attention is directed to the "proposal intent response sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

ELECTRONIC PROPOSAL SUBMISSION: Detailed information regarding the electronic process for submission of proposals may be accessed through the CMB Homepage at the following website by clicking on "E-Proposals".

http://www.niaid.nih.gov/contract/default.htm

PAGE LIMITATIONS: N/A

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE: http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information/Summary of Labor and Direct Costs**
- **Summary of Related Activities**
- **Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration** [When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format *[if applicable]***
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **Annual Technical Progress Report Format for Each Study** [Applicable when contract involves Human Subjects unless it has been determined by the Government that the inclusion of Women and Minority Groups in the Study Population is not appropriate.]
- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Report of Government Owned, Contractor Held Property**
- **Government Property – Schedule ___**
- **Disclosure of Lobbying Activities, OMB Form LLL**

GOVERNMENT FURNISHED EQUIPMENT

Tetramer Facility Equipment

Description	Company	Model	Serial Number
Refrigerator	VWR	GDM-23	12102034
UV Spectrophotometer	Varian	Cary 50 Scan	EL99023367
FPLC	Pharmacia Biotech		67102694 J9 017286
Perfusion Chromatography	Perceptive Biosystems	BioCad/Sprint	727
Refrigerated Incubator/Shaker	New Brunswick	Innova 4330	990122100
Incubator/Shaker	New Brunswick	Innova 4300	990120562
Freezer (-20C)	Laboratory equipment	U202GA14	P19J-427378-PJ
Printer	HP	4000N	USFF236043
Freezer (-80C)	Forma	5463	23218-53
Isotemp Incubator	Fisher	650-d	906N0202
Bench Top Centrifuge	Beckman	Allegra-GR	ALR98L12
Floor Centrifuge	Beckman	J-20	JLY98K01
I-Mac	Apple Computer		XB9109YNEUL
I-Mac	Apple Computer		XA9339LTGVK
I-Mac	Apple Computer		XA9111ALFZK
G4	Apple Computer		XB0322JM-K53-ff06

PACKAGING AND DELIVERY OF THE PROPOSAL

[NOTE TO OFFEROR: Listed below are delivery instructions for the submission of the PAPER copies of your proposal. Instructions for your electronic submission are described above in Electronic Submission Instructions.]

Shipment and marking shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DAIT-02-04
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and 5 unbound copies, with 10 copies of items excluded from electronic submission requirement that you choose to provide in paper format (SOPs, PERTINENT MANUALS, NONSCANNABLE FIGURES OR DATA, AND LETTERS OF COLLABORATION/INTENT.)

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES TO:

If hand delivery or express service	**If using U.S. Postal Service**
Lois Eaton Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Lois Eaton Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with PHSAR 352.215-10, Late Proposals, Modifications of Proposals and Withdrawals of Proposals (NOV 1986).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIT-02-04
RFP Title: NIAID Tetramer Facility

Please review the attached Request for Proposal. Furnish the information requested below and return this page by May 21, 2001. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Lois Eaton
RFP-NIH-NIAID-DAIT-02-04
FAX# (301) 496-0972
Email : le52u@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.nci.nih.gov/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **NAICS CODE AND SIZE STANDARD**

(1) The North American Industry Classification System (NAICS) code for this acquisition is 54171.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

b. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that ONE AWARD will be made from this solicitation and that the award will be made on/about November 30, 2001.

It is anticipated that the award from this solicitation will be a multiple-year, cost-reimbursement, completion type contract with a period of performance of five years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

c. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 63,960 total labor hours for a five-year period. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

d. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

e. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

f. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

g. **COMPARATIVE IMPORTANCE OF PROPOSAL**

You are advised that paramount consideration shall be given to the evaluation of the technical proposal. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

h. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

i. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

j. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, SECTION J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources

information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(8) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protection (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS). The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OHRP, (telephone: 301-496-7005), is recommended.

(e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OHRP and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(9) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

(10) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 at the following web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html

A complete copy of the updated Guidelines is available at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm

The revisions relate to NIH defined Phase III clinical trials and require: a) all proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all contractors to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

The format for the Annual Technical Progress Report for Clinical Research Study Populations (See SECTION J - List of Documents, Exhibits and Other Attachments of this RFP) shall be used in proposal preparation.

(11) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear

and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors may also obtain copies from the contact person listed in the RFP.

(12) **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, FDA and NIH. The frequency of reporting of the conclusions of the monitoring activities should also be described in the plan. The overall elements of each plan may vary depending on the size and complexity of the trial. Examples of monitoring activities to be considered are described in the NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(13) **Care of Live Vertebrate Animals**

The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

(14) **Selection of Offeror**

a) The acceptability of the scientific and technical portion of the research contract proposal will be evaluated by a technical review committee. The committee will evaluate the proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of the contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, the offeror may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(15) **Salary Rate Limitation in Fiscal Year 2001** **

Offerors are advised that pursuant to P.L. 106-554, no NIH Fiscal Year 2001 (October 1, 2000 - September 30, 2001) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an infividual may be permitted to earn outside of duties to the contractor.).

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 106-554 applies only to Fiscal Year 2001 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 106-554 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

***This rate may change periodically. For your information, the rate can be found at: http://www3.opm.gov/oca/01tables/execses/html/01execsc.htm**

(16) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(17) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(18) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

The Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) A Proposal which merely offers to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Cost and Pricing Data

1. **General Instructions**

A. You must provide the following information on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;
(2) Name and address of offeror;
(3) Name and telephone number of point of contact;
(4) Name of contract administration office (if available);
(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(6) Proposed cost; profit or fee; and total;
(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(10) Date of submission; and
(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a

subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://amb.nci.nih.gov/cpi.htm

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

(3) Qualifications of the Offeror

a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(4) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

(5) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(6) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(7) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(8) Travel Costs/Travel Policy

a) **Travel Policy**

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection in the event that two or more offerors are determined to be essentially equal following the evaluation of all factors other than cost or price. In any event, the Government reserves the right to make an award(s) to that offeror(s) whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

(a) Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If concerns are identified and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions and in your Final Proposal Revision (FPR). If, after discussions, concerns still exist, your proposal may not be considered further for award.

(b) Data and Safety Monitoring

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work for the solicitations specific requirements for data and safety monitoring.

The NIAID will evaluate the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human particpants, complexity of study design, and methods for data analysis.

If the information provided about Data and Safety Monitoring is determined to be inadequate, you will be afforded the opportunity to further discuss and/or clarify your plan during discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is considered inadequate, your proposal may not be considered further for award.

(c) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for Phase III clinical trials, it is required that all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable, unless the Government has specified in the Statement of Work that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups.

Where the offeror determines that inclusion of women and minority populations is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIAID will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss, clarify, or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

(d) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are scientific and ethical reasons not to include them.

The offeror's proposal must include a description of plans for including children. If children will be excluded from the research, the proposal must present an acceptable justification for the exclusion. If the offeror determines that exclusion of a specific age range of child is appropriate, the proposal must also address the rationale for such exclusion.

If the information about the inclusion of children is absent or considered inadequate and you are included in the competitive range, you will be afforded the opportunity to further discuss, clarify or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

3. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERA	**WEIGHT**
A. **Technical Approach:**	50
1) Strength and merit of the documented ability of the offeror to produce custom reagents consisting of homogeneous tetrameric peptide-Major Histocompatibility Complex molecules labeled with fluorescent markers that permit antigen-specific detection and quantitative estimation of T lymphocytes.	
2) Strength and merit of the documented ability of the offeror to produce 15-20 tetramers per week including the ability to: synthesize a wide range of Major Histocompatibility Complex (MHC) molecules of human, rodent, and non-human primate origin; refold MHC molecules with peptides; assemble monomeric MHC-peptide complexes into labeled tetramer reagents; perform troubleshooting techniques on problematic production issues; and conduct quality control procedures to assure a functional product. Feasibility of the plan to increase production up to 30 tetramers per week.	
3) Strength and merit of the documented ability and plans to identify, develop, and incorporate new processes, approaches, and technologies for improving tetramer production and advancing tetramer reagent technology.	
B**. Personnel**:	30
1) Strength and merit of the documented availability, training, percent effort, and related experience and expertise of the principal investigator necessary for planning and directing the Facility.	
2) Strength and merit of the documented availability, training, and related experience of all personnel in carrying out the technical and administrative requirements of the contract.	
C. **Facility, Resources and Administration:**	20
1) Strength and merit of the documented ability to commit sufficient and appropriate space, equipment, and physical resources to support the scientific and technical requirements of the contract.	
2) Strength and merit of the documented ability to establish, operate, and maintain a distribution, tracking, and reporting system for a reagent facility.	
TOTAL POINTS =	100